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RUBEN ALCOBA, ESQ. 3399 NW 72 AVENUE SUITE211 MIAMI, FL 33122			EXAMINER RAPILLO, KRISTINE K	
			ART UNIT 4137	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/785,269

Applicant(s)

RIVERA, EDDWIN

Examiner

Kristine K. Rapillo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 1/21/2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Claims

Applicant has added new claims 9 – 16. No claims have been amended or cancelled.

Thus, claims 1 – 16 are pending.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1 – 3, 5 – 6, 8 – 11, 13 – 14, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Andreassen et al. (U.S. Publication No. 2003/0160698 A1) in view of Stasny (U.S. Publication No. 2003/0074234).

In regard to claim 1, Andreassen et al. teaches a method for monitoring the distribution channel of a pharmaceutical drug, comprising the steps of: placing a radio frequency tag on a quantity of a pharmaceutical drug that is to be shipped to a third party (paragraph [0032]); saving the drug's quantity on a database along with the radio frequency tag's identification value that corresponds to the drug (paragraph [0033]); creating an electronic pedigree on the database that will correspond to the radio frequency tag's identification value (paragraphs [0033] and [0038]), where the pedigree is defined in the specification as the complete history (i.e. lot numbers, dosage form,

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shipping history) of the drug as specified by a monitoring agency; loading the pedigree to a website, wherein the website will store the pedigree for third party viewing (paragraph [0048]); and, shipping the pharmaceutical drug to the third party (paragraph [0042]).

Andreassen et al. fails to explicitly teach a method comprising providing the third party with an alias and an access code to the website so that the third party can monitor the pedigree of the drug that is to be received.

Stasny teaches a method comprising providing the third party with an alias and an access code to the website so that the third party can monitor the pedigree of the drug that is to be received (paragraph [0048]);

Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to include a method comprising loading the pedigree to a website, wherein the website will store the pedigree for third party viewing; providing the third party with an alias and an access code to the website so that the third party can monitor the pedigree of the drug that is to be received; and shipping the pharmaceutical drug to the third party as taught by Stasny with the motivation of providing an improved system for distributing pharmaceuticals (paragraph [0010]).

In regard to claim 2, Andreasson et al. teaches a method for monitoring the distribution channel of a pharmaceutical drug as per claim 1, wherein the shipper is the proprietor of the website (paragraph [0042]). Andreasson et al. discloses a method

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wherein the shipper is the manufacturer of the pharmaceutical product, and thus is the proprietor or owner of the web site/internet link.

In regard to claim 3, Andreasson et al. teaches a method for monitoring the distribution channel of a pharmaceutical drug as per claim 2.

Andreasson et al. fails to teach a method comprising the step of giving an alias and an access code to a monitoring agency of the pharmaceutical drug shipped, wherein the access code will allow the agency to see the pedigree of the drug.

Stasny teaches a method comprising the step of giving an alias and an access code to a monitoring agency of the pharmaceutical drug shipped, wherein the access code will allow the agency to see the pedigree of the drug (paragraphs [0046] and [0048]) where Stasny discloses a method where users are given a login name (alias) and password (access code) to enter a web site.

Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to include a method comprising the step of giving an alias and an access code to a monitoring agency of the pharmaceutical drug shipped, wherein the access code will allow the agency to see the pedigree of the drug as taught by Stasny with the motivation to allow a monitoring agency, or others granted an alias and access code, the ability to view data online in regard to the manufacture, conditions for treatment, etc. of a pharmaceutical product (paragraph [0053]).

In regard to claim 5, Andreasson et al. teaches a method for monitoring the distribution channel of a pharmaceutical drug as per claim 1.

Andreasson et al. fails to teach a method wherein an independent party is the proprietor of the website.

Stasny teaches a method wherein a pharmacy is the proprietor of the website (paragraph [0048]). Stasny does not expressly show that the independent party is the proprietor of the website. However, this difference is only found in the non-functional descriptive material and is not functionally involved in the method recited. The function of the proprietor of the website would be performed the same regardless of the proprietor.

Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to include a method wherein an independent party is the proprietor of the website as taught by Stasny with the motivation to allow the proprietor to manipulate the website to include various web pages to correspond to the independent party's customers (paragraph [0047]).

In regard to claim 6, Andreasson et al. teaches a method for monitoring the distribution channel of a pharmaceutical drug as per claim 5.

Andreasson et al. fails to teach a method comprising the step of the independent party giving an alias and an access code to a monitoring agency of the pharmaceutical drug, wherein the access code will allow the agency to see the pedigree of the drug.

Stasny teaches a method comprising the step of a pharmacy giving an alias and an access code to a monitoring agency of the pharmaceutical drug, wherein the access code will allow the agency to see the pedigree of the drug (paragraph [0048]). Stasny does not expressly teach an independent party giving an alias and access code to a monitoring agency. However, this difference is only found in the non-functional descriptive material and is not functionally related to the method recited. The function of giving or providing an alias and access code would not change regardless of who was granting or receiving the access.

The motivation for combining the teachings of Andreasson et al. and Stasny is discussed in the rejection of claim 3, and incorporated herein.

In regard to claim 8, Andreasson et al. teaches a method for monitoring the distribution channel of a pharmaceutical drug as per claim 1.

Andreasson et al. fails to teach a method wherein a monitoring agency of the pharmaceutical drug is the proprietor of the website.

Stasny teaches a method wherein a pharmacy is the proprietor of the website (paragraph [0048]). Stasny does not expressly show that a monitoring agency of the pharmaceutical company is the proprietor of the website. However, this difference is only found in the non-functional descriptive material and is not functionally involved in the method recited. The function of the proprietor of the website would be performed the same regardless of the proprietor.

The motivation for combining the teachings of Andreasson et al. and Stasny is discussed in the rejection of claim 5, and incorporated herein.

In regard to claim 9, Andreassen et al. teaches a method for monitoring the distribution channel of a pharmaceutical drug, comprising the steps of: placing a tag on a quantity of a pharmaceutical drug that is to be shipped to a third party (paragraph [0032]); saving the drug's quantity on a database along with the tag's identification value that corresponds to the drug (paragraph [0033]); and creating an electronic pedigree on the database that will correspond to the tag's identification value (paragraphs [0033], [0037], and [0038]); where the pedigree is defined in the specification as the complete history (i.e. lot numbers, dosage form, shipping history) of the drug as specified by a monitoring agency; loading the pedigree to a website, wherein the website will store the pedigree for third party viewing (paragraph [0048]); and, shipping the pharmaceutical drug to the third party (paragraph [0042]).

Andreassen et al. fails to explicitly teach a method comprising providing the third party with an alias and an access code to the website so that the third party can monitor the pedigree of the drug that is to be received.

Stasny teaches a method comprising providing the third party with an alias and an access code to the website so that the third party can monitor the pedigree of the drug that is to be received (paragraph [0048]).

The motivation for combining the teachings of Andreasson et al. and Stasny is discussed in the rejection of claim 1, and incorporated herein.

In regard to claim 10, Andreasson et al. teaches a method for monitoring the distribution channel of a pharmaceutical drug as per claim 9, wherein the shipper is the proprietor of the website (paragraph [0042]). Andreasson et al. discloses a method wherein the shipper is the manufacturer of the pharmaceutical product, and thus is the proprietor or owner of the web site/internet link.

In regard to claim 11, Andreasson et al. teaches a method for monitoring the distribution channel of a pharmaceutical drug as per claim 10.

Andreasson et al. fails to teach a method comprising the step of giving an alias and an access code to a monitoring agency of the pharmaceutical drug shipped, wherein the access code will allow the agency to see the pedigree of the drug.

Stasny teaches a method comprising the step of giving an alias and an access code to a monitoring agency of the pharmaceutical drug shipped, wherein the access code will allow the agency to see the pedigree of the drug (paragraph [0048]) where Stasny discloses a method where users are given a login name (alias) and password (access code) to enter a web site.

The motivation for combining the teachings of Andreasson et al. and Stasny is discussed in the rejection of claim 3, and incorporated herein.

In regard to claim 13, Andreasson et al. teaches a method for monitoring the distribution channel of a pharmaceutical drug as per claim 9.

Andreasson et al. fails to teach a method wherein an independent party is the proprietor of the website.

Stasny teaches a method wherein a pharmacy is the proprietor of the website (paragraph [0048]). Stasny does not expressly show that the independent party is the proprietor of the website. However, this difference is only found in the non-functional descriptive material and is not functionally involved in the method recited. The function of the proprietor of the website would be performed the same regardless of the proprietor.

The motivation for combining the teachings of Andreasson et al. and Stasny is discussed in the rejection of claim 5, and incorporated herein.

In regard to claim 14, Andreasson et al. teaches a method for monitoring the distribution channel of a pharmaceutical drug as per claim 13.

Andreasson et al. fails to teach a method comprising the step of the independent party giving an alias and an access code to a monitoring agency of the pharmaceutical drug, wherein the access code will allow the agency to see the pedigree of the drug.

Stasny teaches a method comprising the step of the pharmacy giving an alias and an access code to a monitoring agency of the pharmaceutical drug, wherein the access code will allow the agency to see the pedigree of the drug (paragraph [0048]). Andreasson et al. does not expressly teach an independent party giving an alias and access code to a monitoring agency. However, this difference is only found in the non-functional descriptive material and is not functionally related to the method recited. The

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function of giving or providing an alias and access code would not change regardless of who was granting or receiving the access.

The motivation for combining the teachings of Andreasson et al. and Stasny is discussed in the rejection of claim 3, and incorporated herein.

In regard to claim 16, Andreasson et al. teaches a method for monitoring the distribution channel of a pharmaceutical drug as per claim 9.

Andreasson et al. fails to teach a method wherein a monitoring agency of the pharmaceutical drug is the proprietor of the website.

Stasny teaches a method wherein a pharmacy is the proprietor of the website (paragraph [0048]). Stasny does not expressly show that a monitoring agency is the proprietor of the website. However, this difference is only found in the non-functional descriptive material and is not functionally involved in the method recited. The function of the proprietor of the website would be performed the same regardless of the proprietor.

The motivation for combining the teachings of Andreasson et al. and Stasny is discussed in the rejection of claim 5, and incorporated herein.

3. Claims 4, 7, 12, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Andreasson et al. in view of Stasny in further view of Browne (U.S. Publication No. 2003/0216974 A1).

In regard to claim 4, Andreasson et al. teaches a method for monitoring the distribution channel of a pharmaceutical drug as per claim 3.

Andreasson et al. fails to teach a method wherein the alias and access code given to the monitoring agency shall be the same for all the pharmaceutical drugs shipped by the shipper, this allows the monitoring agency to view all of the drugs shipped by the shipper at any given time.

Browne teaches a method wherein the alias and access code given to the monitoring agency shall be the same for all the pharmaceutical drugs shipped by the shipper, this allows the monitoring agency to view all of the drugs shipped by the shipper at any given time (paragraph [0048]).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to include a method wherein the alias and access code given to the monitoring agency shall be the same for all the pharmaceutical drugs shipped by the shipper, this allows the monitoring agency to view all of the drugs shipped by the shipper at any given time as taught by Browne with the motivation of providing a monitoring system for an inventory of drug samples, which would include those drugs shipped to a medical center (paragraph [0029]).

In regard to claim 7, Andreasson et al. teaches a method for monitoring the distribution channel of a pharmaceutical drug as per claim 6.

Andreasson et al. fails to teach a method wherein the alias and access code given to the monitoring agency shall be the same for all the pharmaceutical drugs

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shipped by the shipper, this allows the monitoring agency to view all of the drugs shipped by the shipper at any given time.

Browne teaches a method wherein the alias and access code given to the monitoring agency shall be the same for all the pharmaceutical drugs shipped by the shipper, this allows the monitoring agency to view all of the drugs shipped by the shipper at any given time (paragraph [0048]).

The motivation for combining the teachings of Andreasson et al. and Browne is discussed in the rejection of claim 4, and incorporated herein.

In regard to claim 12, Andreasson et al. teaches a method for monitoring the distribution channel of a pharmaceutical drug as per claim 11.

Andreasson et al. fails to teach a method wherein the alias and access code given to the monitoring agency shall be the same for all the pharmaceutical drugs shipped by the shipper, this allows the monitoring agency to view all of the drugs shipped by the shipper at any given time.

Browne teaches a method wherein the alias and access code given to the monitoring agency shall be the same for all the pharmaceutical drugs shipped by the shipper, this allows the monitoring agency to view all of the drugs shipped by the shipper at any given time (paragraph [0048]).

The motivation for combining the teachings of Andreasson et al. and Browne is discussed in the rejection of claim 4, and incorporated herein.

In regard to claim 15, Andreasson et al. teaches a method for monitoring the distribution channel of a pharmaceutical drug as per claim 14.

Andreasson et al. fails to teach a method wherein the alias and access code given to the monitoring agency shall be the same for all the pharmaceutical drugs shipped by the shipper, this allows the monitoring agency to view all of the drugs shipped by the shipper at any given time.

Browne teaches a method wherein the alias and access code given to the monitoring agency shall be the same for all the pharmaceutical drugs shipped by the shipper, this allows the monitoring agency to view all of the drugs shipped by the shipper at any given time (paragraph [0048]).

The motivation for combining the teachings of Andreasson et al. and Browne is discussed in the rejection of claim 7, and incorporated herein.

Conclusion

4. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- McQuade et al. (U.S. Patent No. 6,952,681) discloses a system to track the distribution of prescription drugs (including controlled substances) using handheld and wireless devices.

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- Subich (U.S. Publication No. 2002/0161607) discloses a pharmaceutical drug sample tracking method using inventory software. Access is granted to pharmaceutical companies as well as physicians.
- Lester et al. (U.S. Patent No. 6,021,392) discloses a system and method for pharmaceutical drug management. A drug distribution center uses an inventory management software program to distribute drugs to patients.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristine K. Rapillo whose telephone number is 571-270-3325. The examiner can normally be reached on Monday to Thursday 7:30 am to 5 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Akm Ullah can be reached on 571-272-2361. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KKR



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